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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/560,723

12/15/2005

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EXAMINER

AEDER, SEAN E

ART UNIT

PAPER NUMBER

1642

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/560,723	Applicant(s) EINSTEIN ET AL.	
	Examiner SEAN E. AEDER	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2 and 16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 is/are allowed.
- 6) ☒ Claim(s) 2 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

The Amendments and Remarks filed 1/8/09 in response to the Office Action of 8/8/08 are acknowledged and have been entered.

Claims 1, 2, and 16 are pending.

Claim 2 has been amended by Applicant.

Claims 1, 2, and 16 are currently under examination.

Rejections Withdrawn

The rejection of claims 2 and 16 under 35 U.S.C. 101 is withdrawn.

Response to Arguments

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 2 and 16 remain rejected under 35 U.S.C. 102(e) as being anticipated by Gish et al (US 2007/0014801 A1; filed 10/12/01) for the reasons stated in the Office Action of 4/10/07, the reasons stated in the Office Action of 11/28/07, for the reasons stated in the Office Action of 8/8/08, and for the reasons set-forth below.

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Amended claim 2 is drawn to nucleic acids which encode a polypeptide comprising the amino acid sequence SEQ ID NO:183. Such nucleic acids encompass nucleic acids that partially encode SEQ ID NO:183 and nucleic acids that encode the entire sequence of SEQ ID NO:183. Therefore, claim 2 encompasses any nucleic acid comprising "a", "t", "g", or "c" nucleotides which partially encode SEQ ID NO:183. Claim 16 is drawn to a diagnostic kit for detection of prostate cancer which comprises nucleic acids which encode a polypeptide comprising the amino acid sequence SEQ ID NO:183 and a detectable label. Further, claim 16 appears to contain a statement reciting purpose or intended use. It is noted that statements of intended purposes or uses are not considered limitations because they merely state an intended use of the invention rather than any distinct definition of any of the claimed invention's limitations (see *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999)). Thus, recitation of statements describing the claimed kit as a kit that is intended to be used to detect prostate cancer are not given patentable weight and are not limitations to the claims.

Gish et al teaches a nucleic acid sequence that is expressed by human prostate cancer cells, SEQ ID NO:271 (see paragraph 7, in particular). SEQ ID NO:271 comprises "a", "t", "g", and "c" nucleotides. Gish et al further teaches a diagnostic kit comprising SEQ ID NO:271 and a detectable label (see paragraphs 13, 30-32, and 190, in particular).

In the Reply of 1/8/09, Applicant argues that Gish does not describe the amino acid sequence of SEQ ID NO:183. Applicant further argues that Gish does not describe a nucleic acid encoding the amino acid sequence of SEQ ID NO:183.

The amendments to the claims and the arguments found in the Reply of 1/8/09 have been carefully considered, but are not deemed persuasive. In regard to the arguments that Gish does not describe the amino acid sequence of SEQ ID NO:183 and that Gish does not describe a nucleic acid encoding the amino acid sequence of SEQ ID NO:183, the amino acid sequence of instant SEQ ID NO:183 is not claimed. Further, the instant claims are drawn to nucleic acids encoding instant SEQ ID NO:183, which include nucleic acids which encode the entire sequence of instant SEQ ID NO:183 *and* nucleic acids such as SEQ ID NO:271 which partially encode instant SEQ ID NO:183.

However, it is noted that the following amendments to instant claim 2 would obviate this rejection: "An isolated nucleic acid, wherein said nucleic acid encodes **the entire amino acid sequence of** a polypeptide comprising the amino acid sequence of SEQ ID NO:183".

Claims 2 and 16 remain rejected under 35 U.S.C. 102(e) as being anticipated by Venter et al (US 6,812,339 B1; 11/2/04) for the reasons stated in the Office Action of 8/8/08, and for the reasons set-forth below.

Venter et al teaches a nucleic acid sequence, SEQ ID NO:30721, which comprises a", "t", "g", and "c" nucleotides and encodes the first 18 amino acids of instant

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SEQ ID NO:183 (see sequence comparison below, in particular). Venter et al further teaches a kit comprising SEQ ID NO:30721 and a detectable label (see liens 35-42 of column 17, in particular).

Alignment Scores:

Pred. No.:	5.7e-07	Length:	601
Score:	90.00	Matches:	18
Percent Similarity:	100.0%	Conservative:	0
Best Local Similarity:	100.0%	Mismatches:	0
Query Match:	100.0%	Indels:	0
DB:	3	Gaps:	0

US-10-560-723-183 (1-18) x US-09-949-016-30721 (1-601)

Qy	1	ValGluThrGluPheHisArgValSerGlnAspGlyLeuAspLeuLeuThrSer	18
Db	283	GTAGAGACGGAGTTTCACCGTGTTAGCCAGGATGGTCTCGATCTCCTGACCTCG	230

In the Reply of 1/8/09, Applicant argues that Venter does not describe an isolated nucleic acid encoding a polypeptide comprising the first 18 amino acids of instant SEQ ID NO:183. Applicant further argues that SEQ ID NO:30721 of Venter does not encode a polypeptide comprising SEQ ID NO:183. Applicant further states that the antisense was cited by the Examiner and not SEQ ID NO:30721. Applicant further argues that SEQ ID NO:30721 cannot be considered a nucleic acid “encoding a polypeptide of SEQ ID NO:183” because the coding frame of the alignment illustrated in the Office Action contains no start codon and contains a stop codon which would prevent expression of any polypeptide comprising SEQ ID NO:183. Applicant further argues that Venter does not disclose a function or utility for SEQ ID NO:30721.

The amendments to the claims and the arguments found in the Reply of 1/8/09 have been carefully considered, but are not deemed persuasive. In regard to arguments that Venter does not describe an isolated nucleic acid encoding a

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polypeptide comprising the first 18 amino acids of instant SEQ ID NO:183 and that SEQ ID NO:30721 of Venter does not encode a polypeptide comprising SEQ ID NO:183, Venter et al teaches complements of instant SEQ ID NO:183 (see lines 26-51 of column 8, in particular). The Office Action of 8/8/08 illustrates the sequence alignment of the complement of SEQ ID NO:30721 and instant SEQ ID NO:183. Even though Venter may indicate said complement would be translated in particular direction, SEQ ID NO:30721 from nucleotide 283 to 230 encodes the first 18 amino acids of SEQ ID NO:183.

In regards to the argument that SEQ ID NO:30721 cannot be considered a nucleic acid "encoding a polypeptide of SEQ ID NO:183" because the coding frame of the alignment illustrated in the Office Action contains no start codon and contains a stop codon which would prevent expression of any polypeptide comprising SEQ ID NO:183, the instant claims do not require expression of a polypeptide. Rather, the instant claims are drawn to an encoding sequence.

In regard to the argument that Venter does not disclose a function or utility for SEQ ID NO:30721, a reference is not required to disclose utility in order to constitute prior art (see MPEP 21.21.04).

However, it is noted that the following amendments to instant claim 2 would obviate this rejection: "An isolated nucleic acid, wherein said nucleic acid encodes **the entire amino acid sequence of** a polypeptide comprising the amino acid sequence of SEQ ID NO:183".

Allowable Subject Matter

Claim 1 is allowed.

Summary

Claims 2 and 16 are rejected.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEAN E. AEDER whose telephone number is (571)272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sean E Aeder/
Primary Examiner, Art Unit 1642